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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,010

06/24/2003

John L. Lawless

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12/23/2004

DORSEY & WHITNEY LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
4 EMBARCADERO CENTER  
SUITE 3400  
SAN FRANCISCO, CA 94111

EXAMINER

CHOOBIN, BARRY

ART UNIT

PAPER NUMBER

2625

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/606,010	LAWLESS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barry Choobin	2625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 21-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>May 28, 2004</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on May 28, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
2. Claims 2-20 have been cancelled and new claims 21-40 are being considered.
3. Currently claims 1 and 21-40 are pending.

### ***Specification***

4. The abstract of the disclosure is objected to because the abstract contains more than 150 words. Correction is required. See MPEP § 608.01(b).

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 and 21-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,584,217. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of instant application are directed to the same inventive concept with different appearances of claims in U.S. Patent No. 6,584,217 (hereafter US , 217).

As to claim 1, US, 217 discloses a method of quantifying data to determine possible presence of a target analyte in a specimen in which a sample of said target analyte is placed upon a membrane having a spot region that, in the presence of said target analyte, changes at Least one optical characteristic relative to surrounding regions of said membrane, the method comprising the following steps (see claim 1, column 17, line 66 through column 18, line 4 wherein placing a sample of said target analyte upon a membrane that includes a spot portion chemically treated such that presence of said target analyte alters a characteristic of said spot portion to permit

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contrast of said spot portion relative to surrounding regions of said membrane to quantify presence of said target analyte);

(a) Alternately and periodically illuminating said surrounding regions of said membrane and said spot region with Light from a Light source. said Light traversing an air path undeflected by any planar optical element disposed between said light source and said membrane (column 18, lines 5-10 wherein alternately and periodically illuminating said spot portion and said surrounding regions of said membrane with light from a light source, said light traveling substantially through air in a path undeflected by any planar optical element disposed between said light source and said membrane);

(b) detecting light reflected from said spot region and from said surround regions of said membrane with light detectors disposed so as to reduce skew error due to irregularities in topography of said membrane, reflected said light traversing an air path undeflected by any planar optical element disposed between said light detectors and said membrane (column 18, lines 11-18 wherein detecting reflected said light with light detectors disposed spaced-apart from each other an angular offset selected from 90 degree and 180 degree. azimuthal, wherein skew error due to irregularities in topography of said membrane is reduced, reflected said light traveling substantially through air in a path undeflected by any planar optical element disposed between said light detectors and said membrane);

(c) signal processing output from said light detectors to discern from optical characteristic information of said spot region relative to optical characteristic information

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of said surrounding regions of said membrane presence of said target analyte (column 18, lines 18-21 wherein using output from said light detectors to measure and to compare said characteristic of light reflected by said spot portion and by said surrounding regions); and

(d) providing an output signal commensurate with an output from said signal processing (column 18, lines 22-23 wherein providing an output signal commensurate with a characteristic of light so measured).

As to claim 21, US, 217 discloses the method of claim 1 (see claim 1 above) and further claims step (b) includes disposing said detectors spaced-apart from each other with an azimuthal angular offset selected from a group consisting of 90 and 180 (this limitation is claimed in claim 1 in step c).

Claim 22 corresponds to claim 2 of US, 217.

Claim 23 corresponds to claim 4 of US, 217.

Claim 24 corresponds to claim 5 of US, 217.

Claim 25 corresponds to claim 6 of US, 217 (note that, claim 25 recites "on a first line" and "on a second line", and in the US 217, claim 6, recites "on a line" and "on a line normal to said line" which correspond to "on a first line" and "on a second line" respectively).

Claim 26 corresponds to claim 7 of US, 217.

Claim 27 corresponds to claim 8 of US, 217.

Claim 28 corresponds to claim 9 of US, 217.

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Claim 29 corresponds to claim 10 of US, 217 (note that claim 10 of US, 217 has more limitations in addition to what claim 29 requires. Is short claim 29 is a broad version of claim 10 in US, 217).

As to claim 30, US, 217 in claim 10 recites the method of claim 1 (see claim 1, above) wherein step (a) includes alternatively and periodically illuminating at a chosen frequency in a range of about 100 Hz to about 10 KHz (column 19, lines 50-52 wherein step (b) includes alternately and periodically illuminating with a chosen frequency in a range of about 100 Hz to about 10 KHz;).

Claim 31 corresponds to claim 11 of US, 217.

Claim 32 corresponds to claim 3 of US, 217.

Claim 33 corresponds to claim 19 of US, 217.

Claim 34 corresponds to claims 12 and 13, claim 13 being dependent on claim 12 (column 20, lines 8-37).

Claim 35 corresponds to claim 14 of US, 217.

Claim 36 corresponds to claim 15 of US, 217.

Claim 37 corresponds to claim 16 of US, 217.

Claim 38 corresponds to claim 17 of US, 217.

Claim 39 corresponds to claim 18 of US, 217.

Claim 40 corresponds to claim 20 of US, 217.

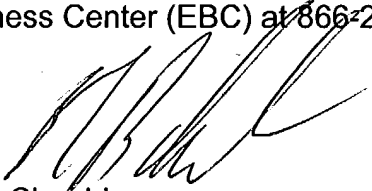
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**CONTACT INFORMATION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Choobin whose telephone number is 703-306-5787. The examiner can normally be reached on M-F 7:30 AM to 18:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 703-308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Barry Choobin  
December 12, 2004